TO: Mail Stop 8 Director of the U.S. Patent & Trademark Office P.O. Box 1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

Alexandria, VA 22313-1450 In Compliance with 35 § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court _____ Northern District of CA ____ on the following X Patents or ☐ Trademarks: DOCKET NO DATE FILED U.S. DISTRICT COURT CV 12-04579 DMR 8/30/2012 1301 Clay St., Suite 400S, Oakland, CA 94612 PLAINTIFF DEFENDANT DR JAMES M SWANSON ALZA CORPORATION PATENT OR DATE OF PATENT HOLDER OF PATENT OR TRADEMARK TRADEMARK NO. OR TRADEMARK *See attached complaint 4 5 In the above-entitled case, the following patent(s) have been included: INCLUDED BY DATE INCLUDED ☐ Amendment ☐ Answer ☐ Cross Bill Other Pleading PATENT OR DATE OF PATENT HOLDER OF PATENT OR TRADEMARK TRADEMARK NO. OR TRADEMARK 2 3 In the above-entitled case, the following decision has been rendered or judgement issued: DECISION/JUDGEMENT CLERK (BY) DEPUTY CLERK DATE Richard W. Wieking

Valerie Kyono

September 5, 2012

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43. As a consequence of Dr. Swanson's justifiable reliance upon ALZA's fraudulent omission, Dr. Swanson has been caused damage in an amount to be proven at trial.

COUNT 3

(BREACH OF FIDUCIARY DUTY)

- 6 44. Dr. Swanson incorporates by reference and realleges all other allegations of the 7 Complaint as though set forth in their entirety herein.
 - 45. ALZA assumed a fiduciary duty towards Dr. Swanson based on, among other things, representing Dr. Swanson in ALZA Corporation v. Kremers Urban, LLC, C.A. No. 10-23-LPS, (D. Del. May 12, 2011)("Kremers litigation").
 - 46. Based on information and belief, in the Kremers litigation during January to February 2011, ALZA attorneys asserted that they represented Prof. Swanson. Specifically, ALZA's litigation attorneys sought to represent Dr. Swanson at his depositions, and filed objections on his behalf and delayed Dr. Swanson's deposition for as long as possible.
 - 47 ALZA through its agents had to be aware of Dr. Swanson's contributions, as evidenced at least in part by the subject matter of the discovery that ALZA was objecting to on Dr. Swanson's behalf. Specifically, the subject matter pertained to Dr. Swanson's inventorship of the '129 patent.
- 19 48. ALZA had a fiduciary duty toward Dr. Swanson to advise him about his inventorship rights, advise him about a potential conflict with ALZA, and to advise him to seek his own counsel.
 - As a result of the fiduciary relationship, ALZA owed Dr. Swanson a duty of loyalty, of candor, of due care and a duty to act in Dr. Swanson's best interests.
 - 50. ALZA breached its fiduciary duty to Dr. Swanson by wrongfully and deceitfully omitting Dr. Swanson as a named inventor of the '129 patent, willfully concealing this omission from Dr. Swanson, and by using the omission for ALZA's economic benefit, and generating billions of dollars in revenue from the manufacture and sale of the drug CONCERTA®.
 - 51 ALZA's actions were detrimental to Dr. Swanson because Dr. Swanson should have benefitted from his invention.

58. The '798 patent is a continuation of the '129 patent. The '798 patent was filed on

administering a pharmaceutically acceptable composition comprising a pharmaceutically acceptable

carrier to said patient in a manner that achieves a substantially ascending methylphenidate plasma

drug concentration over a time period of about 8 hours following said administration." Dr. Swanson

was the first to conceive of and reduce to practice the invention disclosed in the '129 patent,

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including claim 1.

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1	August 12, 2003, and issued on April 24, 2012. Independent claims 1 and 7 include recitation of
2	methylphenidate release amounts over time.
3	 ALZA denied Dr. Swanson the rights and privileges of ownership of the invention
4	embodied in the '129 patent and the '798 patent, and used, benefitted and/or profited from the
5	patented invention(s) without Dr. Swanson's authorization.
6	60. As a direct and proximate result of denying Dr. Swanson's rights and privileges of
7	ownership of the invention(s) embodied in the '129 patent and the '798 patent, ALZA has been
8	unjustly enriched by the use, benefit, and/or profits derived from the patented invention(s), at Dr.
9	Swanson's expense and to his detriment.
10	COUNT 5
11	(INVALIDITY OF THE '129 AND '798 PATENTS UNDER 35 U.S.C. § 102 (f))
12	61. Dr. Swanson incorporates by reference and realleges all other allegations of the
13	Complaint as though set forth in their entirety herein.
14	62. ALZA fraudulently omitted to name Dr. Swanson as an inventor of the '129 and
15	'798 patents.
16	63. Pursuant to 35 U.S.C. § 102(f), the Court should invalidate the '129 and '798 paten
17	for failure to list the proper inventors.
18	COUNT 6
19	(DECLARATION OF UNENFORCEABILITY FOR INEQUITABLE CONDUCT IN
20	PATENT PROCUREMENT)
21	64. Dr. Swanson incorporates by reference and realleges all other allegations of the
22	Complaint as though set forth in their entirety herein.
23	65. Dr. Swanson seeks a declaration that the '129 patent is unenforceable for inequitable
24	conduct in the procurement thereof.
25	66. On information and belief, ALZA and/or individuals associated with prosecution of
26	the patent application knowingly misrepresented material information to the USPTO relating to the
27	inventorship of the '129 patent.

On or about December 6, 1993, Dr. Swanson provided the named inventors of the

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'129 patent with data, ideas, insights, materials, and technologies that were not then publicly available and were known only to Dr. Swanson and that were the product of Dr. Swanson's own research and invention. Indeed, the subject matter of the '129 patent would have been impossible without Dr. Swanson's unique contribution at the time of his participation in the inventive process.

68. .On the morning of December 6, 1993, at 10:30 a.m., Dr. Swanson met with and presented his work on ADHD, including his unique work on the pharmacokinetics and pharmacodynamics of stimulant medications for ADHD, to a group of people at ALZA in Palo Alto, CA, including a number of them later to be named inventors on the '129 patent: Suneel K. Gupta, Andrew C. Lam, Carol A. Christopher, and Samuel R. Saks. Dr. Swanson spoke for over two hours about the pharmacokinetics, pharmacodynamics and tolerance for methylphenidate.

- 69. Dr. Swanson also presented his findings to the ALZA group about the plasma concentrations of methylphenidate and its major metabolite (ritalinic acid) of this regime that produced substantially ascending methylphenidate plasma concentrations across the day. Dr. Swanson brought this knowledge to the meeting at ALZA in Palo Alto, CA and it did not emerge based on discussions with anyone from ALZA, who by their own admissions knew little about ADHD or its treatment.
- 70. On March 8, 2001, the '129 patent was filed naming eleven inventors: Andrew C. Lam, Padmaja Shivanand, Atul D. Ayer, Zahedeh Hatamkhany, Suneel K. Gupta, Diane R. Guinta, Carol A. Christopher, Samuel R. Saks, Lawrence G. Hamel, Jeri D. Wright and Richard G. Wevers. The eleven named inventors signed inventorship oaths asserting that they were the original, first and joint inventors of the subject matter claimed in the application leading to the '129 patent.
- 71. On or about March 8, 2001, ALZA and/or individuals associated with prosecution of the patent application knowingly misrepresented material information to the USPTO relating to the inventorship of the '129 patent by wrongfully not naming Dr. Swanson as an inventor of the '129 patent. This failure to disclose material information constitutes inequitable conduct, which renders the '129 patent unenforceable.
- 72 In September 2006, the eleven named inventors filed a statement in support of a 28 request for correction of inventorship on the '129 patent stating that there was in fact an error in

profits, and advantages derived by ALZA's use of Dr. Swanson's invention(s) embodied in the '129 and '798 patents, without Dr. Swanson's authorization;

- (j) Awarding Dr. Swanson reasonable attorneys' fees and costs as allowed by law; and
- (k) Awarding Dr. Swanson such other relief as this Court deems just and necessary.

August 3/2012

CARR & FERRELL LLP

By: (hale) f + De GERALDP

GERALD P. DODSON
Attorneys for DR. JAMES M. SWANSON

DEMAND FOR JURY TRIAL

Plaintiff Dr. James M. Swanson hereby respectfully demands a trial by jury on all counts to which he is entitled.

Augus 0, 2012

CARR & FERRELL LLP

By: GLOW & Do D

Attorneys for DR. JAMES M. SWANSON

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1 GERALD P. DODSON (SBN 139602) jdodson@carrferrell.com 2 K. BRIAN BATHURST (SBN 211454) bbathurst@carrferrell.com 3 CARR & FERRELL LLP 120 Constitution Avenue Menlo Park, CA 94025 Telephone: (650) 812-3400 Facsimile: (650) 812-3444 6 Attorneys for DR. JAMES M. SWANSON 7 8 9 10 11 DR. JAMES M. SWANSON, an individual, 12 Plaintiff. 13 14 v. 15 ALZA CORPORATION, a corporation, 16 Defendant. 17 18 19 20 21 22 23



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RICHARD W. WIEKING CLERK, U.S. DISTRICT COURT, NORTHERN DISTRICT OF CALIFORM

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

COMPLAINT FOR CORRECTION OF INVENTORSHIP, FRAUD, BREACH OF FIDUCIARY DUTY, UNJUST ENRICHMENT, INVALIDITY, AND DECLARATION OF UNENFORCEABILITY FOR INEOUITABLE CONDUCT IN PATENT PROCUREMENT

DEMAND FOR JURY TRIAL

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COMPLAINT

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DIMA

1	Plaintiff James M. Swanson, Ph.D., ("Dr. Swanson") for his Complaint against Defendant
2	ALZA Corporation ("ALZA") alleges as follows:
3	JURISDICTION, VENUE AND NATURE OF THE ACTION
4	1. This is an action: (a) to correct inventorship under 35 U.S.C. § 256, (b) for fraud, (c)
5	for breach of fiduciary duty, (d) to compensate Dr. Swanson for ALZA's unjust enrichment, (e) for
6	invalidity under 35 U.S.C. § 102 (f), and (f) for a declaration of unenforceability for inequitable
7	conduct in patent procurement.
8	2. This action arises under the Constitution of the United States, Article 1, Section 8, as
9	hereinafter more fully appears. The jurisdiction of this court is founded on 28 U.S.C. § 1331 and 28
10	U.S.C. § 1338 (a).
11	3. Venue is proper in this district under 28 U.S.C. § 1391(b) because a substantial part
12	of the events or omissions giving rise to the claims herein occurred within this district.
13	INTRADISTRICT ASSIGNMENT
14	 This action relates to Intellectual Property and may be assigned to any division
15	pursuant to Civil L.R. 3-2(c).
16	THE PARTIES
17	Plaintiff Dr. Swanson is an individual residing in Seattle, Washington.
18	6. On information and belief, Defendant ALZA is a Delaware corporation, having its
19	principal place of business at 700 Eubanks Drive, Vacaville, CA 95688, where it manufactures the
20	drug CONCERTA® for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in
21	children 6 years of age and older, adolescents, and adults up to age 65.
22	<u>FACTS</u>
23	7. Plaintiff Dr. James M. Swanson is Emeritus Professor of Pediatrics at the University
24	of California Irvine. Dr. Swanson began his employment with the University of California Irvine
25	on June 1, 1980.
26	8. This action seeks to enforce Dr. Swanson's inventorship rights in U.S. Patent No.
27	6,930,129 ("the '129 patent"), entitled "Methods and Devices for Providing Prolonged Drug
28	Therapy." A true and correct copy of the '129 patent is attached as Exhibit A.

4 10 On information and belief, ALZA is the current assignee of the '129 and '798 5 patents, as reflected on the faces of both patents.

11. The '129 and '798 patents provide ALZA with patent protection for excluding competitors from selling products that directly compete with ALZA's CONCERTA®. CONCERTA® was initially approved for marketing by the U.S. Food and Drug Administration ("FDA") in 2000. In 2010, ALZA's parent corporation, Johnson and Johnson, reported \$1,319,000,000.00 in annual revenue from the sale of CONCERTA®.

12. The '129 patent was filed on March 8, 2001 from Mountain View, CA. The '129 patent claims the benefit and priority of U.S. Provisional Patent Application Serial No. 60/030,514 filed on November 12, 1996 from Palo Alto, CA titled "Dosage Form and Method for Administering Drug," U.S. Provisional Patent Application Serial No. 60/031,741 filed on November 25, 1996 from Palo Alto, CA titled "Ascending-Dose Dosage Form," and U.S. Provisional Patent Application Serial No. 60/044,121 filed on April 22, 1997 from Palo Alto, CA 16 titled "Dosage Form and Method for Administering Drug."

13 Claim 9 of U.S. Provisional Patent Application Serial No. 60/030,514 filed on November 12, 1996 from Palo Alto, CA titled "Dosage Form and Method for Administering Drug," recites, "A method for compensating for a decrease in therapeutic activity developed as acute tolerance to a drug in a patient, wherein the method comprises administering to the patient the drug in a continually ascending rate over time to compensate for the decrease in therapeutic activity." Claim 10 of the same provisional patent application recites, "The method for compensating for a decrease in the rapeutic activity according to claim 9, wherein the drug is methylphenidate." The '129 patent issued on August 16, 2005 listing ALZA in Mountain View, CA as 14.

the assignee and naming eleven inventors: Andrew C. Lam, Padmaja Shivanand, Atul D. Ayer, Zahedeh Hatamkhany, Suneel K. Gupta, Diane R. Guinta, Carol A. Christopher, Samuel R. Saks, 28 Lawrence G. Hamel, Jeri D. Wright and Richard G. Weyers. The eleven named inventors signed

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- In September 2006, the named inventors filed a statement in support of a request for 15 correction of inventorship on the '129 patent stating that there was in fact an error in inventorship. To correct the error in inventorship ALZA removed six of the named inventors: Andrew C. Lam, Padmaja Shivanand, Atul D. Ayer, Zahedeh Hatamkhany, Jeri D. Wright and Richard G. Weyers. There was no explanation given to the United States Patent and Trademark Office ("USPTO") as to what the error was that led to the correction in inventorship of the claimed subject matter of the '129 patent.
- 10 16 The '129 patent contains ten claims directed to treatment for Attention Deficit Disorder (hereinafter "ADD") and Attention-Deficit Hyperactivity Disorder ("ADHD") (hereinafter 11 "ADHD"). Claim 1 of the '129 patent recites, "A method for treating Attention-Deficit Disorder or 12 13 Attention-Deficit Hyperactivity Disorder in a patient, wherein the method comprises administering 14 a pharmaceutically acceptable composition comprising a pharmaceutically acceptable carrier to said 15 patient in a manner that achieves a substantially ascending methylphenidate plasma drug 16 concentration over a time period of about 8 hours following said administration." Independent Claim 2 is identical to Claim 1, but changes the "time period" to "about 9.5 hours following administration "
 - The '798 patent is a continuation of the '129 patent. The '798 patent was filed on 17 August 12, 2003, and issued on April 24, 2012. Independent claims 1 and 7 include recitation of methylphenidate release amounts over time.
 - Dr. Swanson only became aware of the claims of the '129 patent at his April 12, 2011 deposition in ALZA's case against Kremers Urban, LLC. Dr. Swanson was never consulted about the '129 patent or interviewed about his unique contributions to the inventions contained in the '129 patent.
- 19 Dr. Swanson was surprised when he found out after his April 12, 2011 deposition that six of the named inventors, including Andrew C. Lam, who was key to modifying the OROS® 28 technology, which Dr. Swanson thought was the basis for the patent, was removed from the '129

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patent. When he heard that the primary claim of the '129 patent was based on achieving a "substantially ascending methylphenidate plasma drug concentration" and not about the drug delivery technology, it became clear to Dr. Swanson that his own ideas from the first meeting at ALZA in Palo Alto, CA about the methylphenidate concentrations after multiple doses were the important basis for the '129 patent -- not the way of achieving the drug delivery by a modification to the OROS® device.

20. Dr. Swanson had spent more than fifteen years engaged in the study and treatment of ADHD prior to meeting with anyone from ALZA about this disorder. Dr. Swanson's research prior to ever meeting with ALZA focused on the treatment of ADHD in children, the subject matter of the '129 patent. Through his research, Dr. Swanson developed procedures for monitoring the cognitive effect of stimulant medication including methylphenidate, and Dr. Swanson is responsible for pioneering the development of improved methods for measuring the plasma concentration of methylphenidate and its metabolite, in order to relate plasma concentrations to clinical efficacy. He also focused on the biochemical and genetic factors related to ADHD.

- 21. On the morning of December 6, 1993, at 10:30 a.m., Dr. Swanson met with and presented his work on ADHD, including his unique work on the pharmacokinetics and pharmacodynamics of stimulant medications for ADHD, to a group of people at ALZA in Palo Alto, CA, including a number of them later to be named inventors on the '129 and '798 patents: Suneel K. Gupta, Andrew C. Lam, Carol A. Christopher, and Samuel R. Saks. Dr. Swanson spoke for over two hours about the pharmacokinetics, pharmacodynamics and tolerance for methylphenidate.
- 22. Dr. Swanson also spoke at the December 6, 1993 meeting at ALZA in Palo Alto, CA about the pharmacokinetics and behavioral time course of three drugs, methylphenidate (Ritalin® and Ritalin SR®), pemoline (Cylert®), and amphetamine (Dexedrine®, Dexedrine Spansules®, and Benzedrine®), and pointed out the problems with each drug and their formulations.
- 23. Dr. Swanson was expressly told at the December 6, 1993 meeting at ALZA in Palo Alto, CA by a number of attendees that no one at ALZA was an expert or had much knowledge about ADHD or treatment for the disorder, and that he should give a comprehensive overview of his

you get Swanson's graphs?"

24. Importantly, before ever meeting with anyone from ALZA, Dr. Swanson knew the optimal pattern for treatment of ADHD was three times a day dosing. Dr. Swanson presented his findings to the ALZA group about the plasma concentrations of methylphenidate and its major metabolite (ritalinic acid) of this regime that produced substantially ascending methylphenidate plasma concentrations across the day. Dr. Swanson brought this knowledge to the meeting at ALZA in Palo Alto, CA and it did not emerge based on discussions with anyone from ALZA, who by their own admissions knew little about ADHD or its treatment.

25. Dr. Swanson also recommended at the December 6, 1993 meeting at ALZA in Palo Alto, CA the need for a once a day pill that was being considered by the ALZA group. His recommendation included a pill with effects lasting for a school day. With early morning dosing, this would be longer than 8 hours (the duration for BID dosing regimen of immediate release methylphenidate) and more in line with a 12 hour duration of the TID regime that he had used in his early work on the PK properties of this drug.

26. Dr. Swanson expressly recalls discussing at the December 6, 1993 meeting at ALZA in Palo Alto, CA why they should attempt to develop a once-a-day pill form of methylphenidate. Dr. Swanson told the ALZA group that it was important to avoid the embarrassment that children experience at school by having to take medication in a public setting supervised by school personnel. This included the embarrassment of having to wear a medicated patch to school, which ALZA was also considering developing at the time for methylphenidate administration.

27. Following this initial meeting with ALZA in Palo Alto, CA on December 6, 1993, Dr. Swanson had numerous subsequent conference calls and meetings discussing the work that was going to be jointly performed by ALZA and Dr. Swanson, in which ALZA confirmed his recommendations for treatment of children with ADHD.

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28. Dr. Swanson incorporates by réference and realleges all other allegations of the Complaint as though set forth in their entirety herein.

29. On numerous occasions, ALZA scientists, including but not limited to Andrew C.

Lam, Padmaja Shivanand, Atul D. Ayer, Zahedeh Hatamkhany, Suneel K. Gupta, Diane R. Guinta,
Carol A. Christopher, Samuel R. Saks, Lawrence G. Hamel, Jeri D. Wright and Richard G. Weyers,
through their patent agents, filed various applications from Palo Alto, CA and from Mountain View,
CA with the USPTO for issuance of one or more United States patents. The USPTO eventually
granted many of these applications resulting in, but not limited to, the '129 patent and the '798
patent. These patents were based on the work of Dr. Swanson.

30. Based upon his activities, contributions, and inventorship prior to the filing date of the '129 patent and the '798 patent, and prior to the filing dates of their underlying U.S. Provisional Patent Applications as specified herein, Dr. Swanson should have been listed as an inventor of the '129 patent and the '798 patent.

- Dr. Swanson contributed substantially to the conception of the invention forming the subject matter of the '129 patent and the '798 patent.
- 32. Dr. Swanson provided the named inventors of the '129 patent and the '798 patent with data, ideas, insights, materials, and technologies that were not then publicly available and were known only to Dr. Swanson and that were the product of Dr. Swanson's own research and invention. Indeed, the subject matter of the '129 patent and the '798 patent would have been impossible without Dr. Swanson's unique contribution at the time of his participation in the inventive process.
- Dr. Swanson was wrongfully not named as an inventor on the subject matter of the
 129 patent and the '798 patent.
 - 34. That omission arose without any deceptive intention of Dr. Swanson.
 - 35. The subject matter of the '129 patent and the '798 patent should be corrected such

1	that Dr. Swanson is named as an inventor thereon, and Dr. Swanson should be accorded any other
2	remedies due him under U.S. patent law.
3	COUNT 2
4	(FRAUD)
5	36. Dr. Swanson incorporates by reference and realleges all other allegations of the
6	Complaint as though set forth in their entirety herein.
7	37. Through their relationship with Dr. Swanson, ALZA made various fraudulent
8	representations and omissions, including fraudulently omitting Dr. Swanson as a named inventor
9	the '129 patent.
10	38. ALZA's fraudulent omission of Dr. Swanson as a named inventor of the '129 pater
11	was material because, among other things, it compromised the validity of the '129 patent.
12	39. Dr. Swanson was unaware of ALZA's fraudulent omission until years later when D
13	Swanson became aware of the claims of the '129 patent at his April 12, 2011 deposition in ALZA
14	case against Kremers Urban, LLC. He was never consulted by ALZA about the '129 patent or
15	interviewed about his unique contributions to the inventions contained in the '129 patent.
16	40. Dr. Swanson was surprised when he found out after his April 12, 2011 deposition
17	that six of the named inventors, including Andrew C. Lam, who was key to modifying the OROS®
18	technology, which Dr. Swanson thought was the basis for the patent, was removed from the '129
19	patent. When he heard that the primary claim of the '129 patent was based on achieving a
20	"substantially ascending methylphenidate plasma drug concentration" and not about the drug
21	delivery technology, it became clear to Dr. Swanson that his own ideas from the first meeting at
22	ALZA in Palo Alto, CA about the methylphenidate concentrations after multiple doses were the
23	important basis for the '129 patent not the way of achieving the drug delivery by a modification
24	to the OROS® device.
25	Al Al 7A mode its froughtlest emission of Dr. Commun.

patent to deny Dr. Swanson of his rightful professional and economic expectancies.

42. Dr. Swanson reasonably and justifiably relied upon the truth of ALZA's fraudulent 28 omission, had a right to rely thereupon, and was unaware of the truth because of ALZA's